

### **REMARKS**

#### **Amendments**

Claim 5 has been amended to limit the NK3 antagonist specifically to talnetant and to limit to treatment. Basis for this amendment can be found page 1 lines 3-5 of the application as filed. Original claim 6 has been deleted without prejudice and the subsequent claims renumbered accordingly.

#### **102**

Emonds-Alt et al does not disclose the use of talnetant for treating bipolar disorder. The amended claims are therefore not anticipated.

#### **103**

Amended claims 5-7 are inventive over Emonds-Alt et al. Emonds-Alt et al is directed to the use of the NK3 antagonist osanetant for the treatment of depressive disorders, disclosing in particular “depressive disorders associated with bipolar disorder” (see Col 1, line 37-38).

The objective technical problem is the use of the NK3 antagonist, talnetant, to treat bipolar disorder.

The person skilled in the art, having read Emonds-Alt et al and faced with the objective technical problem, would not have arrived at the invention described in the claims of the present application. Emonds-Alt et al describes the use of the specific NK3 antagonist osanetant for the treatment of depression, including depressive disorders associated with bipolar disorder. Bipolar disorder is a complicated disorder which has different variations and sub-categories which include both mania and depression.

Depressive disorder associated with bipolar disorder is a particular sub-category of bipolar disorder. Therefore the teaching of Emonds-Alt et al is restricted to the use of osanentan for treating depression associated with bipolar disorder.

There is no teaching in document Emonds-Alt et al that an NK3 antagonist would be useful in the treatment of bipolar disorder in the wider sense, such as mania. Therefore, there is no teaching that talnetant would be useful for treating bipolar disorder in the wider sense or indeed any teaching that it could be useful in treating depression associated with bipolar disorder. Thus, the skilled person at the priority date of the present invention would have had no motivation to try to use talnetant to treat bipolar disorder.

In addition, the skilled person at the priority date of the application would be aware of the controversy surrounding the use of antidepressants for treating bipolar disorder, as discussed in S Nassir Ghaemi, Douglas J Hsu, Federico Soldani, Frederick K Goodwin (2003) "Antidepressants in bipolar disorder: the case for caution" *Bipolar Disorders* 5 (6), 421–433, enclosed herein. The document describes that the use of antidepressants for treating bipolar disorder can lead to the patient switching into manic episodes or rapid cycling, which needs further medication to control. The skilled person, being aware of this document at the priority date of the title application, looking for an improved treatment for bipolar disorder would not choose the antidepressant osanentan as a start point.

Amended claims 5-7 are therefore inventive.

Conclusion

Please enter into the record the amendments set forth herein above. All of the issues raised by the Examiner have been addressed. If any issues remain to be resolved in the application, the Examiner is invited to contact the undersigned at the number provided.

Respectfully submitted,

/JamesMKanagy/

James M. Kanagy  
Attorney for Applicants  
Registration No. 29,550

GLAXOSMITHKLINE  
Corporate Intellectual Property - UW2220  
P.O. Box 1539  
King of Prussia, PA 19406-0939  
Phone (610) 270-5014  
Fax (610) 270-5090